(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 June 2002 (06.06.2002)

PCT

(10) International Publication Number
WO 02/43519 A1

(51) International Patent Classification[7]: A43B 17/10, A61F 13/06

(21) International Application Number: PCT/US01/17717

(22) International Filing Date: 1 June 2001 (01.06.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PCT/US00/32531
29 November 2000 (29.11.2000) US

(71) Applicant *(for all designated States except US)*: **THE PROCTER & GAMBLE COMPANY** [US/US]; One Procter & Gamble Plaza, Cincinnati, OH 45202 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **MINABE, Yoko** [JP/JP]; 1-18-18-505, Moriminamimachi, Higashinada-ku, Kobe, Hyogo 658-0011 (JP). **NAKAGAWA, Yasue** [JP/JP]; 1431-14-602, Mikage-Aza-Shironoomae, Mikage-cho, Higashinada-ku, Kobe, Hyogo 658-0056 (JP). **YOSHIKAWA, Ken** [JP/JP]; 8-6-8, Amon Court II #211, Motoyamaminami-cho, Higashinada-ku, Kobe, Hyogo 658-0015 (JP). **INOUE, Tomoko** [JP/JP]; 4-3-203, Matsushita-cho, Nishinomiya, 662-0962 (JP). **YOSHIKAWA, Akikazu** [JP/JP]; 3-6-23, Sumiyoshimiyamachi, Higashinada-ku, Kobe, Hyogo 658-0053 (JP).

(74) Common Representative: **THE PROCTER & GAMBLE COMPANY**; c/o Mr. Reed, T., David, 5299 Spring Grove Avenue, Cincinnati, OH 45217 (US).

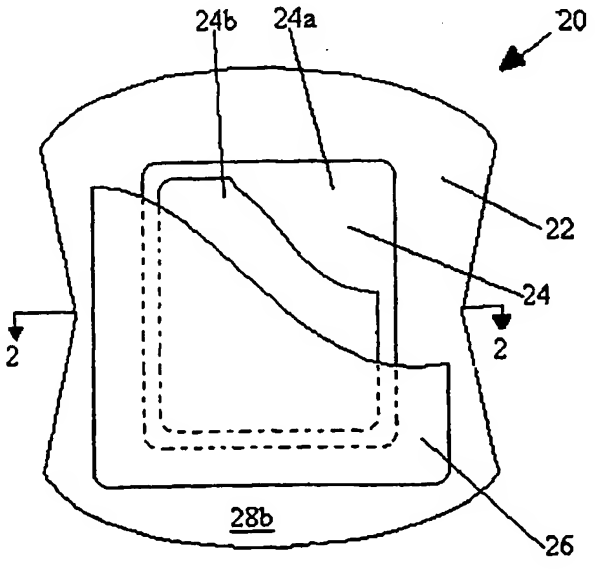
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) Title: DISPOSABLE SELF-ADHESIVE FOOT PATCH FOR ANATOMICAL SUPPORT FOR THE REARFOOT AND FOREFOOT AREAS



(57) Abstract: A disposable self-adhesive foot patch (20) with improved breathability, that is adhesively applied to the foot for anatomical support.

WO 02/43519 A1

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DISPOSABLE SELF-ADHESIVE FOOT PATCH FOR ANATOMICAL SUPPORT FOR THE REARFOOT AND FOREFOOT AREAS

This application is a continuation-in-part of International PCT Application No. PCT/00/32531 filed November 29, 2000 in the United States Receiving Office and claims priority to that application.

FIELD OF THE INVENTION

The present invention relates to a disposable self-adhesive foot patch for application to the foot and lower ankle area. Specifically, the present invention relates to a disposable self-adhesive foot patch that provides anatomical support to the foot and lower ankle area to prevent and reduce fatigue and discomfort in the feet and legs.

BACKGROUND OF THE INVENTION

During each footfall in walking, forces are acting between the ground and the foot. These forces are usually referred to as ground reaction forces (GRF). They can be quantified using appropriate measuring devices. The order of magnitude of GRF for walking is 1 to 1.5 times a person's body weight. Studies have shown that there are typically two distinct phases of force when there is foot-ground interaction. First is when the foot collides with the ground and second is when the foot pushes off from the ground. The two phases of force have different consequences with respect to the human musculoskeletal system.

Custom shaped foot devices tend to be made from durable, rigid material that is worn every day. These devices tend to be expensive and require modification subsequent to fitting. Additionally custom devices are typically bulky and require replacement when the size of the foot changes. An example of such a device is shown in U.S. Pat. No. 4,360,027.

Other foot devices have been made from materials that deform under pressure. Such devices are exemplified by U.S. Pat. No. 6,138,383. These foot devices are designed for extended use in a person's footwear. These devices take the shape of a shoe insert covering either the entire bottom of the foot or some smaller area thereof.

Typically shoe inserts have difficulties in maintaining a cushioning and structural support for extended periods of time. The inserts can be bulky and make shoes uncomfortable to the foot. The inserts are subject to unsanitary conditions inside of the shoe environment including bacteria, dirt, sweat and odors. Also, these inserts cannot be used with all types of footwear, especially footwear that does not have an entirely enclosed construction such as sandals and some women's shoes. However, even devices that can be worn in sandals or other open shoe structures still pose problems with the sweat produced by the foot.

The average human foot produces between 200 mL to 500 mL of moisture a day from more than 250,000 sweat glands in the foot. Thus, the humidity within a shoe can be quite high. If an item is adhesively placed on the skin, the skin becomes wet and overhydration can occur. This effects the skin of the wearer and the adhesive properties of the item placed onto the skin of the foot. The addition of the frictional forces produced by walking, a product adhesively applied to the foot will have a tendency to peel off or migrate during movement.

Skin occlusion can negatively impact comfort and cause negative changes to skin structure. Skin overhydration can be a common problem in products that are attached to the skin. This can increase the chance of skin irritation and skin softening (maceration). As a result of maceration, the skin is more subject to abrasion due to normal movement, and skin disorders such as erythema (i.e. redness), heat rash, abrasion, pressure marks and skin barrier loss.

Such problems have been addressed with medical dressings. Patches or pads that attach directly to the skin are well known in the medical industry for wound dressings. While these types of bandages address the breathability issues (i.e. vapor permeability), they lack the anatomical structural support necessary for a foot device.

Another property of medical wound dressings is liquid absorption. Often medical wound dressings are designed to absorb fluids that emanate from the wound. Similarly, in the foot area, sweat glands produce enough fluid to result in maceration of the skin. A disposable article that can absorb some of the sweat produced by the foot is desirable. However, medical wound dressings are designed to absorb and hold bodily fluids. This type of design is undesirable for foot devices since the area available in a wearer's shoe is limited and an

increase in volume of the foot device can cause discomfort. Therefore it is desirable to have an a disposable self-adhesive foot patch that has wicking properties to help keep the foot area dry.

Patches or pads that attach directly to the foot have been disclosed previously. Exemplary are JP Pat. No. 8-98868A (Kokai) which discloses an adhesive arch support, JP Pat. No. 11-255635A (Kokai) which discloses adhesive foot patches for stimulating reflex points, and U.S. Pat. No. 6,120,473 which discloses an adhesive arch support. These references fail to address the important problem of foot wetness. As such, these devices can lead to foot discomfort if worn for an extended period of time. These devices do not provide a wicking element to remove the sweat from the foot to be transported away from the skin of the foot that can also alleviate overhydration problems. Furthermore, these devices ignore the importances of anatomical support for the forefoot and rear foot area.

Accordingly, the need exists for a disposable device that provides anatomical structural support for the foot and lower ankle area that can be applied directly or indirectly to the skin and that is breathable to allow vapor permeability and liquid permeability.

SUMMARY OF THE INVENTION

The present invention relates to a disposable self-adhesive foot patch comprising an adherent article having a first side and second side wherein the adherent article has a MVTR value of at least 200 g/24 h/ m^2; the first side of the adherent article being provided with an adhesive; and an anatomical support material having a MVTR value of at least 200 g/24 h/ m^2, and having a first side and second side; wherein the first side of the anatomical support material is attached to the second side of the adherent article; wherein the first side of the adherent article is placed against the foot or lower ankle area and adhered thereto by the adhesive. The present invention also relates to a disposable self-adhesive foot patch comprising an adherent article having a first side and second side wherein the adherent article has a MVTR value of at least 200 g/24 h/ m^2; the first side of the adherent article being provided with an adhesive; and an anatomical support material having a MVTR value of at least 200 g/24 h/ m^2, and having a first side and second side; wherein the second side of the anatomical support material is attached to the first side of the adherent article;

wherein the anatomical support material is placed against the foot or lower ankle area and adhered thereto by the adhesive.

It has now been found that the present invention can provide anatomical support to the foot to prevent and reduce fatigue and discomfort in the foot and leg areas more effectively than traditional noncustomized foot devices. The present invention allows the wearer to position the foot device in a position to provide the greatest benefit to the wearer. The present invention also allows the wearer to select the properties they are most interested in using, e.g. whether the wearer wants heel support, toe support, ball area of the foot support, or any combination thereof.

The present invention is designed to be disposable to address the unsanitary conditions often found in permanent inserts. The present invention may be attached to the foot so as to not restrict the use of the present invention to closed shoe structures. The disposable self-adhesive foot patch can provide anatomical support with or without footwear. The ability of the disposable self-adhesive foot patch to deliver anatomical support is derived from the wearer being able to place an effective material to the desired portion of the foot. The wearer is able to place, for example, a heel patch in a position that is most effective to the wearer without having the disposable self-adhesive foot patch specifically fitted to the wearer's foot. The present invention is breathable to avoid the moisture problems associated with the foot area. The present invention may also be clear or skin-toned in appearance to address concerns over discreetness in wearing foot devices that are visible when the person has open footwear or no footwear. Additionally, the present invention may be light in weight to allow comfortable wearing in footwear and to reduce fatigue than can result from heavier foot devices.

These and other features, aspects, advantages, and variations of the present invention will become evident to those skilled in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

While the specification concludes with claims particularly pointing out and distinctly claiming the invention, it is believed that the invention will be better understood from the following description of the accompanying drawings, not necessarily drawn to scale, in which:

Fig. 1 is an partial cut away top view of a preferred embodiment of the disposable self-adhesive foot patch of the present invention; and

Fig. 2 is a sectional side view of the disposable self-adhesive foot patch in Fig. 1 taken along line 2-2.

DETAILED DESCRIPTION OF THE INVENTION

All percentages, ratios and proportions herein are by weight of the final composition, unless otherwise specified. All temperatures are in degrees Celsius (°C) unless otherwise specified. All documents cited are incorporated herein by reference in their entireties. Citation of any reference is not an admission regarding any determination as to its availability as prior art to the claimed invention.

The term "disposable" is used herein to describe articles that are not intended to be laundered or otherwise restored or reused as an article (i.e. they are intended to be discarded after a single use and, preferably, to be recycled, composted or otherwise disposed of in an environmentally compatible manner.)

The term "anatomical support" refers to skeletal and/or muscular and/or soft tissue support received from the present invention including, but not limited to cushioning, shock absorption, and bracing properties.

When the foot collides with the ground, the heel of the foot, for about 80% of individuals, strikes the ground first. This impact is generally short in nature and compression and traction of soft tissues in the rearfoot area provide shock-absorbing functions to dissipate the GRF. However, the mechanical integrity of these soft tissues decreases with age. Studies have associated the degeneration of the soft tissue of the rearfoot area and the effect of impact forces on the rearfoot area with chronic and degenerative injuries such as plantar fasciitis and heel spurs. To assist the body in adjusting to the impact forces products that deform easily under load and dissipate energy decrease the impact force on the rearfoot area and help decrease injuries to the foot.

After the impact of the heel striking the ground, a normal human gait continues on to a second phase of force that occurs when the foot pushes off from the ground. The second phase affects the medial longitudinal arch of the foot. The foot goes through a series of motions during a normal gait. The motions are summarized below.

Table 1

	Heel Strike	Stance	Toe-Off	Swing
Foot position	Supinated	Pronated	Supinated	Pronated
Function	Stability	Mobility	Stability	Mobility

While this process is a normal part of a human gait, excessive pronation or eversion is the source of many lower extremity pathologies, including muscle fatigue and inflammation, foot and knee joint pain, tendinitis, ligament strain, and even neurological damage. Excessive pronation or eversion also renders the gait less efficient since time and effort is wasted in pronating and supination.

The disposable self-adhesive foot patch of the present invention may be used to alleviate the problems described above, while not being limited to a theory, by attempting to mimic the soft tissue cushioning of the forefoot and rearfoot areas.

THE DISPOSABLE SELF-ADHESIVE FOOT PATCH

The disposable self-adhesive foot patch (20) shown in Figs. 1 and 2 comprises an adherent article (22), an anatomical support material (24), and an enclosing material (26).

The adherent article (22) has an adherent article first side (28a) that is intermittently coated with an adhesive (not shown) and an adherent article second side (28b). The anatomical support material (24) preferably comprises a deformable foam (24a) and a stiff foam (24b), however the anatomical support material (24) may be comprised of one material. The deformable foam (24a) is attached to the adherent article second side (28b). The stiff foam (24b) superposes over the deformable foam (24a). Enclosing material (26) superposes over the anatomical support material (24) and adhesively attaching to the adherent article second side (28b). The adherent article first side (28a) is attached to the skin of the forefoot or rearfoot area during use by the wearer.

The disposable self-adhesive foot patch according to the present invention should be light in weight. The disposable self-adhesive foot patch should be between 100 grams to 0.0001 grams, preferably between 50 grams and 0.0001 grams, and most preferably between 15 grams and 0.0001 grams.

ADHERENT ARTICLE

Numerous disclosures are directed to improving wearer skin condition by reducing the risk of creating overhydrated skin or by allowing already overhydrated skin to dehydrate to a level closer to unoccluded skin when an article is applied to or near the skin. Water molecules are is continuously escaping from unoccluded skin into the surrounding air. However, the placement of an article near or on the skin allows the relative humidity near the surface of the skin to be close to 100%. Air is still present around the skin but essentially there is no loss water from the skin to the surrounding air, that is, water molecules leave the skin for the air at about the same rate as water molecules absorb into the skin from the air. The accumulation of moisture creates the overhydration in the skin.

More or less breathable devices or materials are described in U.S. Pat. Nos. 4,627,847, 4,648,876, 4,578,069, 4,713,068, 4,758,339, 4,833,172, 4,923,650, 5,254,111, 5,492,751, 5,599,420 and 5,628,737, in published European Patent applications EP 315,013 and EP 710,471, and in published PCT applications WO 95/16,562 and WO 95/16,746.

The adherent article preferably provides adhesive properties that allow the foot patch to applied to the skin under walking conditions but relatively easy to remove after use with gas and liquid permeability to prevent overhydration of the skin.

The adherent article is preferably compliant, soft feeling, and non-irritating to the wearer's skin. Further, the adherent article may be liquid permeable, permitting liquids to readily penetrate through its thickness. A suitable adherent article may be manufactured from a wide range of materials such as woven and nonwoven materials (i.e., a nonwoven web of fibers); polymeric materials such as apertured formed thermoplastic films, apertured plastic films, and hydroformer thermoplastic films; porous foams; reticulated foams; reticulated thermoplastic films; and thermoplastic scrims. Suitable woven and nonwoven materials can comprise natural fibers (e.g., wood or cotton fibers), synthetic fibers (e.g., polymeric fibers such as polyester, polypropylene, or polyethylene fibers) or from a combination of natural and synthetic fibers. When the adherent article comprises a nonwoven web, the web may be manufactured by a wide number of known techniques. For example, the web

may be spunbonded, carded, wet-laid, melt-blown, hydroapertured, hydroentangled, combinations of the above, or the like. Such nonwoven webs may be bonded using means known to the art, such as chemical bonding, latex bonding, thermal bonding, and the like. The adherent article of the present invention may comprise a single layer or it may comprise more than one layer or material.

The adherent article may be coated on the surface or impregnated into the adherent article with any suitable adhesive. A suitable adhesive is an adhesive that gives the requisite degree of adhesion and which in non-toxic and non-allergenic. The adhesive may or may not be vapor permeable. Ideally, the degree of adhesion should be such that the disposable self-adhesive foot patch remains in place for the duration of the user's use. The disposable self-adhesive foot patch should be relatively easily removable at the end of the use.

An essential element of the present invention is the use of materials that are sufficiently permeable to gases, such as air, water vapor, or other volatile materials. Apart from diffusion, gases or vapor can pass through a solid material by small capillary transport (slow), or convective transport (fast). Permeability can be assessed by the well-known Mass Vapor Transmission Rate (MVTR), expressed in units of g/24 h/m^2 under various driving forces. For purposes of the present invention, the method, as is described in the TEST METHODS section below, involves calcium chloride, which adsorbs moisture passing through the test specimen that is exposed to an environmental relative humidity of 75% at 40°C. An alternative method of assessing gas permeability uses an air permeability test (also described in the TEST METHODS section below), whereby air is sucked through a test specimen under defined conditions such as a specific pressure drop across the sample. As the air permeability test relates to high penetration rates, it is more applicable to materials allowing convective flow (fast) rather than the diffusional or capillary transport dominated (slow) materials.

A suitable material for use as the adherent article (22) for purposes of the present invention has a MVTR value of at least about 200 g/24 h/m^2. Preferably, the MVTR of the adherent article (22) of the present invention is at least about 400 g/24 h/m^2. More preferably, the MVTR of the adherent article (22) is also least 500 g/24 h/m^2. Examples of such materials suitable for use in the present invention include woven and nonwoven fiber materials, apertured polymeric

films, porous foams, reticulated foams, reticulated polymeric films, and polymeric scrims that are coated or impregnated with a suitable adhesive.

With respect to the present invention, materials manufactured or treated to be permeable can be classified as follows:

Table 2

MVTR	Permeability Range (g/m^2 /24 h)
non-permeable	up to about 200
low permeability	about 200-500
medium permeability	about 500-1000
high permeability	about 1000-2000
very high permeability	more than about 2000

As noted above, materials with low breathability, that is materials with MVTR values greater than about 200-500 g/24 h/m^2 are effective in allowing transport of moisture vapor from the void space between a wearer's body and the present invention.

The adherent article (22) may be made using a hydrophilic substrate to promote rapid transfer of sweat through the adherent article (22). If the material is hydrophobic, at least the upper surface of the adherent article (22) is treated to be hydrophilic so that liquids will transfer there through more rapidly. This diminishes the likelihood that fluids will flow off the adherent article (22) rather than being drawn through the adherent article (22). The adherent article (22) can be rendered hydrophilic by treating it with a surfactant or silica. Suitable methods for treating the adherent article (22) with a surfactant or sillica include spraying the adherent article (22) with the surfactant and/or silica and immersing the adherent article (22) into the surfactant and/or silica.

ANATOMICAL SUPPORT MATERIAL

The anatomical support material (24) preferably is non-irritating to the wearer's skin and provides the desired properties necessary to provide anatomical support to the wearer. Desired properties are dependent upon the function and use of the anatomical support material (24). The anatomical support material (24) of the present invention may comprise a single material or

it may comprise more than one material. Exemplary materials include natural and man-made materials such as polymeric foams, gels, laminates, resins, rubbers, or other viscoelastic materials.

There are no purely elastic or purely viscous materials in nature; there is always a combination of these two properties. All materials comprise elastic and viscous properties and are referred to as viscoelastic. A material is considered "elastic" if it is predominantly elastic, i.e. if it has only to small extent viscous properties. On the other hand, a material is "viscous", if it has predominately viscous properties, i.e. only to a small extent elastic properties. Elastic materials store energy by converting mechanical work into potential energy, which is recoverable. Viscous materials do not store energy, but when stressed dissipate energy as heat as the viscous materials flow. This dissipation gives damped motion.

The anatomical support material (24) for a rearfoot area will preferably comprise at least a viscous material to help decrease and dissipate the striking force of the foot as it comes into contact with the ground, however elastic material may be include to give a "bouncy" feel to the anatomical support material (24). The anatomical support material (24) for a forefoot area is preferably made of elastic material to help return energy to the push-off portion of the human gait.

Preferred properties of the anatomical support material (24), includeing adequate reaction to dynamic compression, rebound resiliency, hardness, vertical wicking, absorbency characteristics such as absorbency under pressure, and vapor permeability, are discussed in detail below.

A) Dynamic Compression

The anatomical support material (24) preferably has mechanical properties that it can be subjected to dynamic compression. The average human gait repeats on a frequency of approximately 1 Hz and any materials attached to the human foot is subjected to the same frequency of force. It is preferable to have an anatomical support material (24) that has elastic and viscosity properties that can respond to these recurring forces. The elasticity and viscosity of viscoelatic material can be measured under dynamic compression conditions. Preferably the anatomical support material (24) has a dynamic modulus of elasticity between about 1.0 x 104 Pa at 1 Hz and about

2.65 x 105 Pa at 1 Hz as measured by JIS K7244-4 described below in TEST METHODS.

B) Rebound Resiliency

The anatomical support material (24) preferably has mechanical properties that demonstrate rebound resiliency. It is preferable that the anatomical support material (24) gives a cushioning effect, but not completely "bottom out" by being compressed to a two-dimensional structure.

C) Hardness

The anatomical support material (24) preferably has mechanical properties that demonstrate an appropriate amount of hardness. As stated above, the anatomical support material (24) preferably gives a cushioning effect. However, it is also preferable that the anatomical support material (24) gives some support to the foot area. It is preferred that the anatomical support material (24) has between about 1 to about 32 Hs – SRIS C.

D) Vertical Wicking Performance

The anatomical support material (24) preferably has mechanical properties that demonstrate vertical wicking performance. Vertical wicking performance is the ability of the anatomical support material (24) to transfer body liquids away from the surface of the skin into the anatomical support material (24).

E) Absorbent Capacity and Absorbent Capacity Under Pressure

The anatomical support material (24) preferably has mechanical properties that demonstrate absorbent capacity and absorbent capacity under pressure. Absorbent capacity is the total amount of test fluid which a given anatomical support material (24) sample will absorb into its structure per unit mass of solid material in the sample. Absorbent capacity under pressure refers to the amount of that fluid held under no confining pressure (free capacity) that the anatomical support material (24) would retain within its structure when the sample is subjected to compressive force.

F) Vapor Permeability

The anatomical support material (24) preferably has mechanical properties that demonstrate vapor permeability. The anatomical support material (24) should have a MVTR at least about 200 g/24 h/m^2, preferably at least about 400 g/24 h/m^2, and even more preferably at least about 500 g/24 h/m^2 as described in TEST METHOD below.

If foam materials are used for the anatomical support material (24), such foam material can have a relatively open celled or a relatively closed celled character. The type of character depends upon whether and/or the extent to which, the cell walls or boundaries, i.e. the cell windows, are filled or taken up with material. For purposes of the present invention, a foam material in which about 80% of its cells which have intercellular openings or "windows" which are large enough to permit ready fluid transfer from one cell to the other within the foam structure are relatively open-celled foam structures. For purposes of the present invention, a foam material in which about 20% of its cells which have intercellular openings or "windows" which are large enough to permit ready fluid transfer from one cell to the other within the foam structure are relatively closed-celled foam structures.

ENCLOSING MATERIAL

The enclosing material (26) can be made from any material that was previously described as desirable for the adherent article (22) above, specifically having a MVTR value of at least about 200 g/24 h/m^2, preferably at least about 400 g/24 h/m^2, and more preferably at least about 500 g/24 h/m^2.

OTHER ELEMENTS

The foot patch of the present invention may optionally comprise other elements that can benefit a user. Examples of such other elements include a moisture absorption layer that temporally retains the moisture and then allows water vapor to permeate out of the disposable self-adhesive foot patch; medicinal additives such as anti-fungal, anti-microbial, cooling or heating stimulating compounds and any combination thereof; malodor control such as deodorants, zeolite, perfumes and any combination thereof; compositions giving skin benefits such as moisturizing lotions, niacinamide powder, callus softening compositions, corn removal composition, wart removal compositions, and any similar products; and massaging or other circulation benefits may be optionally included in the present invention; and any combination of the foregoing elements.

TEST METHODS

Moisture Vapor Transmission Rate

The Moisture Vapor Transmission Rate (MVTR) determines the amount of moisture adsorbed by calcium chloride in a "up" like container that is covered by a test specimen where the moisture source is a controlled temperature/humidity environment (40°+-.3°C./75.+-.3% relative humidity) separated from the calcium chloride by the test specimen.

The sample holding a cup is a cylinder with an inner diameter of 30 mm and an inside height from bottom to top flange of 49 mm. A flange having a circular opening to match the opening of the cylinder can be fixed by screws, and a silicone rubber sealing ring with an opening matching the inner diameter of the cup, fits between the top flange and the cylinder. The test specimen, in this case either the entire foot patch or the components of the foot patch taken individually, is positioned such that it covers the cylinder opening. The specimen is tightly fixed between the silicone rubber sealing and the upper flange of the cylinder so it acts as a barrier to moisture transport.

The equipment as well as the test specimen should be equilibrated to the temperature of the controlled environment prior to testing.

The absorbent desiccant material is calcium chloride, such as can be purchased from Wako Pure Chemical Industries Ltd., Richmond, Va. under the product designation 030-00525. If kept in a sealed bottle, it can be used directly. It also can be sieved to remove lumps, or excessive amounts of fines, if existing. It also can be dried at 200°C. for about 4 hours.

The calcium chloride is weighed (15.0.+-.0.02 g) into the cup, and tapped lightly so as to level it out, such that the surface is about 1 cm from the top of the cup.

A test sample is placed flat and overlapping with the seal over the opening, and the seal and the top flange are affixed by the screws without over tightening. The total weight of the cup assembly is accurately recorded to four decimal places, and the assembly is placed into the constant temperature/humidity chamber.

After 5 hours exposure to the test humidity (without opening of chamber), the sample is removed and immediately covered tightly with a non-vapor permeable plastic film such as SARAN WRAP. After cooling about 30 minutes to allow for temperature equilibration, the plastic film is removed and the assembly is reweighed.

The MVTR value is then calculated by determining the moisture increase over 5 hours due to transport through the circular opening and converting the result to units of "g/24 h/m^2".

For each test, three replicates should be run, the resulting values will be averaged, and the result rounded to the nearest 100 value.

Overall, this method is applicable to thin films, multi-layer laminates and the like. Experience has shown, that typical standard deviations range between 50 and 250 g/24 h/m^2 for averaged values of up to about 5000 g/24 h/m^2.

Air Permeability

The air permeability is determined by measuring the time in which a standard volume of air is drawn through the test specimen at a constant pressure and temperature. This test is particularly suited to materials having relatively high permeability to gases, such as nonwovens, apertured films and the like.

The test is operated in a temperature and humidity controlled environment, at 22°.+-.2°C. and 50.+-.2% relative humidity. The test specimen has to be conditioned for at least 2 hours.

Suitable test equipment is manufactured by Hoppe & Schneider GmbH, Heidelberg, Germany, under the designation "Textiluhr nach Kretschmar". The apparatus is essentially a bellows in a vertical arrangement, with its upper end being mounted in a fixed position, and the lower end being releasably held at its upper position, which can be loosened by means of a release handle to slide under controlled conditions to the lower position, thereby increasing the volume inside the bellows by pulling air through the test specimen which covers the air inlet opening at the upper end of the bellows. The test specimen is firmly held to cover the air inlet opening by means of a fastening ring having an area of either 5 cm^2 or 10 cm^2 (allows for different samples sizes and/or different permeability ranges). If the 10 cm^2 ring is used, the sample should be at least 55 mm wide, for the 5 cm^2 ring a sample width of at least 35 mm is required. For both, the samples should have a length of about 150 mm.

Optionally, the sample holding device can comprise a stretching element, such as to enable measurement of elastic materials under stretched conditions.

The equipment comprises a stopwatch (1/100 sec increments) which automatically measures the time between the operation of the release handle,

which starts the sliding of the bellows, and the bottom of the bellows reaching its lower or stop position.

The air permeability of the material can then be calculated by dividing a constant (provided by the supplier for each individual test apparatus; K is about 200.000 for a tested area of 5 cm^2, and about 400.000 for an area of 10 cm^2) by the time as measured in seconds, resulting in units of: liters/cm^2 /sec.
The test is repeated once for each test sample, and should be repeated on 10 samples to provide a representative value for a material.

Dynamic Modulus of Elasticity

Dynamic modulus of elasticity can be measured by the method defined by JIS K7244-4. The dynamic modulus of elasticity of the present invention was measured with a sample size having 10 mm width, 10 mm length, and 5 mm in height. The sample was exposed to a frequency range of 1 Hz with a dynamic strain of 0.1% at 23°C.

The example of the invention is set forth hereinafter by way of illustration and is not intended to be in any way limiting of the invention.

EXAMPLE 1

The embodiment depicted in Figs. 1 and 2 is intended for use as a heel patch. The adhesive article (22) and enclosing material (26) comprise brown body tape sold under the tradename KINESHIO TAPE or KINESIO TEX by Kineshio K.K. Japan. The adhesive used for the adhesive article (22) and enclosing material (26) is an acrylic synthetic-resin and is intermittently applied by 2 mm wide stripes with 1 mm space between stripes to the adhesive article (22). The adhesive article (22) side with the adhesive is placed onto the foot and/or lower ankle area. The anatomical support material (24) comprises a deformable foam (24a) that is open celled polyurethane foam and a stiff foam (24b) that is a closed cell foam material sold under the tradename LION SHEET. The deformable foam (24a) is placed next to the adhesive article (22) and the stiff foam (24b) is placed next to the deformable foam (24a). Niacinamide powder for skin care benefits and a zeolite sheet more moisture absorbency included in the disposable self-adhesive foot patch (20).

It is understood that the preferred embodiment set forth above is not to be limiting on the scope and spirit of the present invention.

WHAT IS CLAIMED IS:

1. A disposable self-adhesive foot patch comprising:
   (a) an adherent article having a first side and second side wherein the adherent article has a MVTR value of at least 200 g/24 h/ m^2; the first side of the adherent article being provided with an adhesive; and
   (b) an anatomical support material having a MVTR value of at least 200 g/24 h/ m^2, and having a first side and second side; wherein the first side of the anatomical support material is attached to the second side of the adherent article;

wherein the first side of the adherent article is placed against the foot or lower ankle area and adhered thereto by the adhesive.

2. A disposable self-adhesive foot patch comprising:
   (a) an adherent article having a first side and second side wherein the adherent article has a MVTR value of at least 200 g/24 h/ m^2; the first side of the adherent article being provided with an adhesive; and
   (b) an anatomical support material having a MVTR value of at least 200 g/24 h/ m^2, and having a first side and second side; wherein the second side of the anatomical support material is attached to the first side of the adherent article;

wherein the anatomical support material is placed against the foot or lower ankle area and adhered thereto by the adhesive.

3. The disposable self-adhesive foot patch of Claim 1 wherein the disposable self-adhesive foot patch further comprises an enclosing article encompassing the anatomical support material and is attached to the second side of the adherent article.

4. The disposable self-adhesive foot patch of Claim 2 wherein the disposable self-adhesive foot patch further comprises an enclosing article encompassing the anatomical support material and is attached to the first side of the adherent article.

5. The disposable self-adhesive foot patch of Claim 1 or Claim 2 wherein the anatomical support material is one or more viscoelastic materials.

6. The disposable self-adhesive foot patch of Claim 3 or Claim 4 wherein the adherent article, anatomical support material, enclosing material, or any combination thereof is clear or skin-toned in appearance.

7. The disposable self-adhesive foot patch of Claim 1 or Claim 2 further comprising a liquid absorption layer. medicinal additives, malodor control additives, skin care compositions, massaging features, and combinations thereof.

8. A disposable self-adhesive foot patch for anatomical support comprising:
   (a) an adherent article that is clear or skin-toned in appearance having a first side and second side wherein the adherent article's MVTR values are at least 200 g/24 h/m^2; the first side of the adherent article being provided with an adhesive;
   (b) an anatomical support material with an MVTR value of at least 200 g/24 h/m^2 having a first side and second side wherein the first side of the anatomical support material is attached to the second side of the adherent article and the anatomical support material is comprised of one or more material;
   (c) an enclosing material having a MVTR value of at least 200 g/24 h/m^2 and clear or skin-toned in appearance, the enclosing material having a first and second side; wherein the enclosing material superposed over the anatomical support material and where the enclosing material is connecting to the second side of the adherent article;

wherein the first side of the adherent article is placed against the foot or lower ankle area and adhered thereto by the adhesive.

9. A disposable self-adhesive foot patch for anatomical support comprising:
   (a) a adherent article having a first side and second side that is clear or skin-toned in appearance wherein the adherent article's MVTR values are at least 200 g/24 h/m^2; the first side being

(b) a anatomical support material with an MVTR value of at least 200 g/24 h/m^2, the anatomical support material having a first and second side wherein the second side of the anatomical support material is attached to the first side of the adherent article and the anatomical support material is comprised of one or more viscoelastic material;

(c) an enclosing material with a MVTR value of at least 200 g/24 h/m^2, having a first and second side, the enclosing material further being clear or skin-toned in appearance; wherein the enclosing material encompasses the anatomical support material to form a pouch by connecting to the second side of the adherent article;

wherein the anatomical support material is placed against the foot or lower ankle area and attached by the first side of the adherent article.

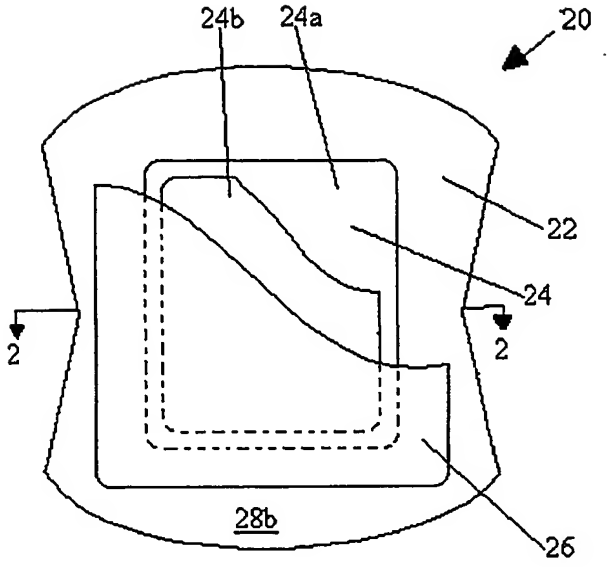


Fig. 1

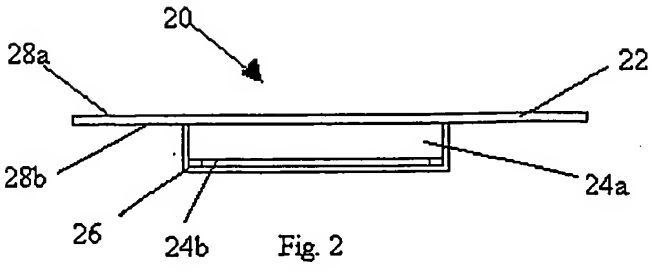


Fig. 2

INTERNATIONAL SEARCH REPORT

Int ial Application No
PC /US 01/17717

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A43B17/10 A61F13/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A43B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 051 249 A (SAMUELSEN PETER BOMAN) 18 April 2000 (2000-04-18) column 3, line 57 -column 4, line 11 column 8, line 48 - line 61; figure 3	1-9
A	US 6 120 473 A (OLIVERIO CATHERINE H) 19 September 2000 (2000-09-19) cited in the application the whole document	1,2,8,9
A	PATENT ABSTRACTS OF JAPAN vol. 1996, no. 08, 30 August 1996 (1996-08-30) & JP 08 098868 A (KOBAYASHI PHARMACEUT CO LTD), 16 April 1996 (1996-04-16) cited in the application abstract	1,2,8,9

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 March 2002	18/03/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Schölvinck, T.S.

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte I Application No
PCI/US 01/17717

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	PATENT ABSTRACTS OF JAPAN vol. 1999, no. 14, 22 December 1999 (1999-12-22) & JP 11 255635 A (SEKISUI CHEM CO LTD), 21 September 1999 (1999-09-21) cited in the application abstract	1,2,8,9

INTERNATIONAL SEARCH REPORT

Inte ·al Application No
PC : 01/17717

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6051249 A	18-04-2000	AT 195066 T	15-08-2000
		AU 4482796 A	14-08-1996
		DE 69609595 D1	07-09-2000
		DE 69609595 T2	05-04-2001
		WO 9622754 A1	01-08-1996
		DK 805663 T3	18-12-2000
		EP 0805663 A1	12-11-1997
		ES 2150096 T3	16-11-2000
US 6120473 A	19-09-2000	NONE	
JP 08098868 A	16-04-1996	NONE	
JP 11255635 A	21-09-1999	NONE	